UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,669	10/16/2003	Wayne L. Ryan	12642.0065.NPUS01	2668

23369 7590 09/29/2009

HOWREY LLP-HN
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DRIVE, SUITE 200
FALLS CHURCH, VA 22042-7195

EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/605,669	RYAN, WAYNE L.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,10,14-18,20,21,23 and 28-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,10,14-18,20,21,23 and 28-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 7/20/09 to claims 1-5, 7, 8, 10, 14-18, 20, 21, 23, and 27 have been entered. Claims 6, 9, 11-13, 19, 22, and 24-26 have been canceled. Claims 28-50 have been added. Claims 1-5, 7, 8, 10, 14-18, 20, 21, 23, and 28-50 remain pending in the current application, all of which are being considered on their merits. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Election/Restrictions

Applicant's elections of the species "diazolidinyl urea," "EDTA," "whole blood," and "a packaging means for transporting said collection device" in the reply filed on 3/29/06 and the species "a flow cytometer" and "HIV" in the reply filed on 2/18/09 are still in effect over the claims.

Specification

The disclosure remains objected to because of the following informalities: It recites various trademarks, including "VACUTAINER PLUS" and "HEMOGARD" at page 11; "TROLOX" at page 17; and "KATHON" and "OMADINE" at page 21, **without providing generic terminology for these products.** Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might

adversely affect their validity as trademarks. Appropriate correction is required for all trade names referenced in the specification.

It is noted that applicant has amended the specification to include the "trademark" symbol for each of these trade names, but applicant has not complied with the requirement to provide generic terminology for each one. The objection stands.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, 8, 10, 14-18, 20, 21, 23, and 34-39 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. Evidence that claims 1-5, 7, 8, 10, 14-18, 20, 21, 23, and 34-39 fail to correspond in scope with that which applicants regard as the invention can be found in the reply filed 7/20/09. In that paper, applicant has stated, "The amended claims clearly set forth the feature that the amount of the compound is very small relative to the final volume within the container or tube **once the sample is drawn."** See reply, page 21, paragraph continuing from previous page; emphasis added. Applicant further urges that "the claims … do not recite cells as a necessary component of the device." See reply, page 20, paragraph 2. This statement indicates that the invention is different from what is defined in the claim(s) because the ratio between the volume of the compounds within the tube and the volume of cells collected into the tube is repeatedly cited by applicant as the basis for patentability in the invention. The

examiner submits that the claims do not actually define the invention, given applicant's urging that the volume ratio is inventive.

Because claims 2-5, 7, 8, 10, 15-18, 20, 21, 23, and 34-39 depend variously from indefinite claims 1 and 14 and do not clarify these points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claims 1-5, 7, 8, 10, 14-18, 20, 21, 23, and 28-50 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to include reference numerals, which the examiner assumes is an attempt to incorporate the aspects of the drawings into the claims. This is wholly improper. 35 U.S.C. § 112, second paragraph, requires that the claims themselves define the invention, i.e. without any need to refer to drawings. The claims should be amended to delete all references to reference numerals.

Claim 14 is drawn to a device "for collecting mammalian cells" comprising "a collection container for collecting a final composition"; claims 1 and 27 are drawn to methods for making and using this container. The claims are confusing because the preamble does not match the elements of the claim; it is not clear whether the "final composition" is the same as the "mammalian cells." Furthermore, the term "final" in claim 14 implies a time element, which is confusing in the context of a composition (which has no time element). Claims 1, 14, and 27 refer to "a tube for collecting a final

composition having a volume of 100 parts," which is confusing because it is not clear whether "100 parts" is the volume of the tube or the final composition.

The term "parts" (which is recited in independent claims 1, 14, 27, and 40) is not a generally accepted unit of volume; volume is a description of a three-dimensional space. Furthermore, the description at step (a) of claim 1, e.g., is queried; it is not clear whether the "volume of 300 parts" refers to the tube or the final composition. Finally, the language "preloading compounds including [compounds], wherein said compounds are in a volume of no greater than 2 parts" is confusing because it is not clear whether the "volume" relates to the whole set of preloaded compounds (i.e., those at the first line of step (b) of claim 1) or just to the enumerated anticoagulant agent and fixative (the transitional phrase "including" is open language that permits the presence of additional elements; see M.P.E.P. § 2111.03). Clarification of all of these points is required.

Because claims 2-5, 7, 8, 10, 15-18, 20, 21, 23, 28-39, and 41-48 depend variously from indefinite claims 1, 14, 27, and 40 and do not clarify these points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Regarding the relevant indefiniteness rejections of record, applicant alleges generally that the amendments to the claims definitely define the invention. See reply, pages 16-21. These arguments have been fully considered, but they are not persuasive. Neither the amendments nor the arguments adequately address the new points raised.

Claims 3, 4, 16, 17, 30-33, 36-39, 43, and 44 recite concentrations ("g/mL"), but there is no basis provided in the claims for these comparative limitations. Clarification is required. Applicant alleges that the claims "refer to weight/volume," a point not disputed

by the examiner. What is at issue is which weight and which volume are being referenced. The independent claims refer to a device, a tube, and a final composition, all of which have volume. They also recite “compounds including an anticoagulant agent and a fixative agent,” i.e. three possible weights (since “including” is open-claim language, the “compounds” may include additional unrecited components). For example, it is not clear whether the "g/mL" in claim 3 refers to “grams of fixative agent per tube” or “grams of fixative agent per mL of compounds added in step (b)." Clarification of this point is still required, especially given the fact that the basis for patentability is allegedly the relative amounts of the components present in the device.

Claim 14 requires a container having “an open end and a closed end" with “a closure at said open end of said container,” which is confusing. It is not clear how an end of a tube can be both open and have a closure.. Applicant alleges that this problem has been addressed by amendment, but it is not clear to which amendment applicant refers. None of the amendments to claim 14 address this problem. Clarification is still required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7, 8, 10, 14-17, and 20, 21, 23, 27-50 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan (1998, U.S. Patent 5,849,517;

reference A3 on 2/20/09 IDS) taken in view of Camiener (1999, U.S. Patent 5,977,153; reference A4 on 2/20/09 IDS) and Glover et al. (1975, U.S. Patent 3,879,295) and Louderback (1976, U.S. Patent 3,973,913). In the interest of compact prosecution, the claims are interpreted as being drawn to a collection device comprising an anticoagulant and diazolidinyl urea (DU, a fixative), wherein the device has at least a partial vacuum inside. Some claims are drawn to methods for making and using such a device. In some dependent claims, the anticoagulant is EDTA. In some dependent claims, the cells to be preserved are those in whole blood. In some dependent claims, the components in the device are sterilized and/or freeze-dried. Some claims list downstream applications for the device.

Ryan teaches collecting whole blood samples in a vacutainer containing EDTA and adding a fixative solution containing DU, then processing the sample using flow cytometry (Specific Examples I and II at columns 8-9). Ryan teaches that the amount of DU to include in the collection device is that effective to fix or stabilize cells and tissues while preserving antigenic sites thereof (column 7, lines 39-45; see also column 6, lines 56-60, and column 3, lines 30-39). Ryan teaches that the amount of DU may vary (column 4, lines 49-51; column 17, line 66, through column 18, line 1; and claims 4, 8, and 19). Ryan teaches that whole blood preserved in their device may be screened for HIV (Specific Examples XIII and XIV at columns 16-18). Ryan teaches that DU is a disinfectant (column 17, lines 65-66), so it necessarily sterilizes the device. Ryan teaches shipping samples preserved using the device to distant sites, implying use of a packaging means for such transporting (column 3, lines 45-46).

Ryan does not teach an embodiment in which DU and an anticoagulant (EDTA, for example) are contained within a collection device with an internal pressure lower than atmospheric pressure. Ryan does not teach an embodiment in which the active agents are freeze-dried.

Camiener teaches that DU may be evaporated to a solid, dry mass that maintains its fixative ability (Examples 1 and 3 at columns 8 and 9). Camiener suggests a composition comprising DU and EDTA (column 8, lines 13-15). Camiener teaches that lyophilization (freeze-drying) may also be used to dry the fixative (column 9, lines 31-32). The dried fixative of Camiener is suitable for preserving biological materials, including blood (claim 1 and column 7, lines 42-47).

Glover teaches a tissue collection device that holds a vacuum inside and may be sealed with a stopper (Abstract). The title of Glover refers to the device as a vacutainer. The device of Glover contains a vacuum sufficient to allow cells to be collected (column 6, lines 36-41). Glover teaches adding a clotting agent after the sample is collected (column 6, lines 53-55).

Louderback teaches that EDTA is an anticoagulant (column 3, lines 30-32).

A person of ordinary skill in the art would have had a reasonable expectation of success in including the dried DU of Camiener within the EDTA-containing evacuated device of Ryan for the purpose of preserving cells because Camiener teaches that drying DU does not affect its preservative properties. The skilled artisan would have had a further expectation of success in employing the evacuated tissue collection device of Glover as the “vacutainer” of Ryan because Glover’s device can be used to collect

blood. The person of ordinary skill in the art would have had a further reasonable expectation in combining the teachings of Ryan and Glover because Louderback teaches that the EDTA in the container of Ryan prevents clotting, and because Glover's teaching that clotting agents should be added once blood has been collected clearly indicates that clotting prior to processing is undesirable.

The skilled artisan would have been motivated to substitute the dried DU of Camiener for the DU solution taught by Ryan because Camiener teaches that DU maintains its fixative ability after being dried and is useful for fixing and preserving cells, which is the same utility sought by Ryan.

The selection of the amount of DU and EDTA to include in the collection device would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Ryan teaches that these amounts may be modified as necessary. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include DU and EDTA within an evacuated container in amounts sufficient to preserve the morphology and antigenic sites of cells stored in said container because Ryan teaches that DU has such preservative activity and because Glover teaches such a partially evacuated device for collecting cells. It would have been further obvious to the skilled artisan in the art at the time the invention was made to dry DU and/or EDTA within the collection device because Camiener teaches that such dried compositions are useful for fixing and preserving collected cells.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that Ryan does not teach the instantly claimed "sample to reagent ratio." See reply, page 26, paragraph 2; and page 30, last paragraph et seq. Applicant alleges that Ryan does not teach direct blood draw and did not consider the factors involved in that process. See page 26, last paragraph et seq. Applicant alleges that there is no need for an anticoagulant in Camiener's composition. See reply, page 27, paragraph 3. Applicant alleges that Glover does not teach preloading the tube with agents prior to sample collection and therefore teaches away from doing so. See reply, page 27, last paragraph et seq.; and page 31, paragraph 3. Applicant alleges that Louderback does not teach the invention. See reply, page 28, paragraph 2. Applicant alleges that the invention provides stabilization with "only a small amount of fixative, and in the presence of other reagents." See reply, page 29, last paragraph et seq. These arguments have been fully considered, but they are not persuasive.

As discussed at length in the indefiniteness rejections, the claims do not define an invention in which the "sample to reagent ratio" is as high as applicant's arguments contend. The claims to the device do not appear to include cells (see also applicant's comments at page 20), so ratio arguments are not germane to the patentability of the device. The method claims require introducing "a volume of no greater than 2 parts of compounds that include an anticoagulant agent and a fixative agent" (see claim 40, step (b), e.g.), and as discussed above, the transitional phrase "including" is synonymous

with “comprising." Furthermore, the term “parts” is not a clear unit of volume. Therefore, the claims do not effectively limit the amount of any of the components.

The comments regarding “direct blood draw” and the collection of samples in developing countries are not relevant to the claims, since none of them refers to these concepts in any way, implicitly or explicitly.

Applicant’s comment that Camiener’s composition does not need an anticoagulant is not supported by evidence. Applicant’s comment that Camiener does not suggest the usefulness of their composition in preserving blood is without clear basis. Camiener teaches that their composition may be used to preserve blood. See column 7, lines 42-47, in particular line 47. Applicant has provided no evidence that preserving samples for analysis by flow cytometry has materially distinct requirements than the preserving taught by the cited art. This argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration.

The fact that Glover’s working example requires adding clotting agents after the addition of a blood sample is not a teaching away from carrying out the steps in reverse order. Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the

problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See M.P.E.P. §2123. Furthermore, in *In re Burhans, 154 F.2d 690, 69 USPQ 330* (CCPA 1946), the court found that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. In *In re Gibson, 39 F.2d 975, 5 USPQ 230* (CCPA 1930), the court found that selection of any order of mixing ingredients is *prima facie* obvious. See M.P.E.P. § 2144. In any case, Ryan's teaching of preloading a tube with anticoagulants prior to blood collection provides motivation to do so; the rejection here rests on a simple substitution of Glover's tube for Ryan's. There is no need for each reference in an obviousness rejection to teach every element of the claimed invention.

The comments regarding Louderback amount to piecemeal analysis of that reference.One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Even if applicant had identified some outcome of using some small amount of fixative relative to the sample size (which the examiner does not concede, and which the claims do not actually recite), the invention would still not necessarily be patentable. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Applicant should provide some evidence that selecting the low ratio alleged to be inventive was not suggested by the prior art and that choosing a low ratio yields unexpected results that are practically and statistically significant.

Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan, Camiener, Glover, and Louderback as applied to claims 1-4, 7, 8, 10, 14-17, and 20, 21, 23, 27-50 above, and further in view of Deich et al. (1992, U.S. Patent 5,110,908).

The teachings of Ryan, Camiener, Glover, and Louderback are relied upon as above. Furthermore, Ryan teaches that samples collected in the device may be used in the preparation of vaccines (column 3, lines 35-39).

Ryan, Camiener, Glover, and Louderback do not teach including a polyacrylic acid in the collection device.

Deich teaches that polyacrylic acid is an adjuvant suitable for use in vaccine production (column 21, line 44, through column 22, line 6).

A person of ordinary skill in the art would have had a reasonable expectation of success in including the polyacrylic acid of Deich in the collection device of Ryan taken in view of Camiener, Glover, and Louderback because Deich teaches that polyacrylic acid may be contacted with vaccines. The skilled artisan would have been motivated to include polyacrylic acid in the collection device to facilitate the production of vaccines, as taught by Ryan.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polyacrylic acid of Deich in the collection device of Ryan taken in view of Camiener, Glover, and Louderback because both are taught as being useful in vaccine production.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicants rely on arguments traversing the above rejection to traverse this rejection. Therefore, the response set forth above to arguments also applies to this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 27 and 40-50 are/remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 8, and 11-13 of U.S. Patent No. 5,849,517 in view of Glover et al. (1975, U.S. Patent 3,879,295).

Claim 27 is interpreted as being drawn to a method for preparing cells for analysis comprising providing an at least partially evacuated device comprising an anticoagulant agent and DU and collecting cells in said device. Claim 40 is drawn to a method similar to that of claim 27, except the sample is limited to blood cells. Instant claim 41 requires that the solution further comprise EDTA. Claim 1 of the ‘517 patent is drawn to a method of preserving tissue samples by suspending them in a solution comprises DU in one embodiment; claims 7 and 8 of the ‘517 patent allow that the solution further comprise EDTA. Instant claim 40 is drawn to a method of collecting blood; claim 12 of the '517 patent allows that the sample may be blood. Claims 4, 5, 8, and 11 of the '517 patent suggest that the amounts of DU and EDTA may be varied; instant claims 43 and 44 address these amounts.

The claims of the ‘517 patent are silent as to the method being carried out in an at least partially evacuated container.

Glover teaches a tissue collection device that holds a vacuum inside and may be sealed with a stopper (Abstract). The device of Glover contains a vacuum sufficient to allow cells to be collected (column 6, lines 36-41).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to carry out the preservation method of the '517 claims in the device of Glover because Glover's device is explicitly taught as being useful for tissue and cell collection. A blood sample collected into the device of Glover comprising the DU and EDTA of the '517 claims would inherently form a solution in which the sample becomes suspended.

Applicant points out that Glover is not commonly owned by the assignee of the instant application and the '517 patent and alleges that this fact disqualifies it from use in a double patenting rejection. See reply, page 33, paragraph 4. These arguments have been fully considered, but they are not persuasive. There is absolutely no requirement in M.P.E.P. § 804 that all references used to support a double patenting rejection be commonly owned. Obviousness-type double patenting requires the same analysis set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 § U.S.C. 103. Clearly, if a secondary reference combined with patented claims renders the instant claims obvious, the requirements of M.P.E.P. § 804 are met.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651